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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,803	04/15/2004	Nancy Smyth-Templeton	60251-CON2(47992)	8697
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EDWARDS & ANGELL, LLP				
P.O. BOX 55874				
BOSTON, MA 02205				
			EXAMINER	
			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1613	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,803

Applicant(s)

SMYTH-TEMPLETON ET AL.

Examiner

Gollamudi S Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4-15-04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The preliminary amendment dated 4-15-04 is acknowledged.

Claims included in the prosecution are 18 and 19. .

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is confusing. What is it applicant is claiming? A composite liposome which has a invaginated vase-like structure or which will form the invaginated vase-like structure. If it is the latter, then how does the vase-like structure form? The step involved should be recited. It is also unclear as recited, whether two separate bilayer structures are involved or one liposome with two bilayers and the active agent is outside the top bilayer. Clarification is requested.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

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See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,413,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic 'liposome' and 'sandwich liposome' encompass the specific 'sandwich liposome' recited in claims 1 and 2 of said patent. Instant process of preparation which is the same as the patented process (claim 3), but drawn to generic 'biologically active agent' encompasses the DNA in the patented claim.

3. Claims 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 1-7 of U.S. Patent No. 6,770,291. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic 'liposome' and 'sandwich liposome' encompass the specific 'sandwich liposome' recited in claims 1 and 2 of said patent. Instant process of preparation which is the same as the patented process (claim 3), but drawn to generic 'biologically active agent' encompasses the DNA in the patented claim.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO93/25673 of record.

WO discloses liposomes made of DOTAP, cholesterol derivative and DNA (note the abstract, Examples, example 2 in particular). The liposomes can be targeted (page 29). Since WO discloses liposomes containing the same components and prepared by

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sonication, the burden is upon applicant to show that the prior art liposomes are different from instant liposomes.

6. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Parks (5,230,899).

Claim 18 can be interpreted as a liposome having a bilayer within a bilayer and the presence of the biologically active agent present outside and inside since forming an invaginated vase like structure is an intended function. In essence, this reads on a multilamellar liposomes having a hydrophilic agent which is inside and outside the liposomes.

Park discloses multilamellar liposomes containing arginine (biologically active agent) (abstract, col. 4, lines 46-60, Examples, example 2 in particular and claims). Since the claim recites the intended function, the burden is shifted to applicant to show that Park's liposomes do not form the same claimed structure.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Debs (5,827,703).

Debs discloses liposomes containing DOTAP, Cholesterol derivative and DNA (note the abstract and Example 2 on columns 19-20. Since Debs discloses liposomes

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containing the same components and prepared by sonication, the burden is upon applicant to show that the prior art liposomes are different from instant liposomes.

7. 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Felgner (5,580,859).

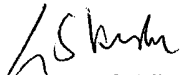
Felgner discloses instant liposomes; liposomes contain DOTAP, cholesterol and nucleic acids (note col. 26, line 51 and example 6). Since Felgner discloses liposomes containing the same components and prepared by sonication, the burden is upon applicant to show that the prior art liposomes are different from instant liposomes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK